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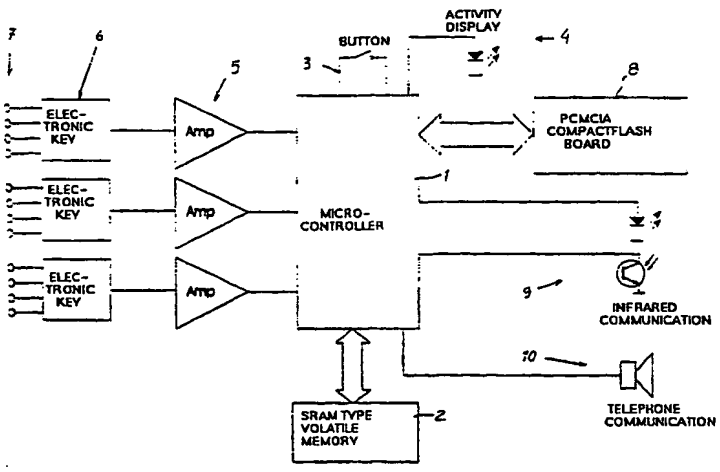
(54) Title: MULTI-FUNCTIONAL EQUIPMENT FOR DIAGNOSING AND MONITORING OF ELECTRICAL/CARDIAC ACTIVITY



(57) Abstract

Multi-functional equipment for diagnosing and monitoring of electrical/cardiac activity, comprising a microcontroller (1) connected to a SRAM type volatile memory (2), being said microcontroller (1) activated from a button or switch (3); the microcontroller (1) also comprises an activity display (4) and it is connected to amplification blocks (5), each one connected to electronic keys (6), the latter connected to the representative block of inlets (7), which are twelve in number.

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"MULTI-FUNCTIONAL EQUIPMENT FOR DIAGNOSING AND MONITORING OF ELECTRICAL/CARDIAC ACTIVITY".

The invention refers to an equipment specially developed to enable the diagnosing and monitoring of electrical/cardiac activity, considering four operation modes.

As it is well known, the diagnosing and monitoring of electrical/cardiac activity include up to four operation modes, which are ECG, SAECG, event recorder and Holter.

As per the present art, each one of the mentioned operation modes is carried or enabled by a specific type of equipment, since there is, so far, no single equipment comprising all the four mentioned modes efficiently.

An object of the present invention is to provide a single equipment which efficiently performs all the four above-mentioned operation modes.

Another feature of the present invention is related to an equipment, which can be used in procedures comprising the four operation modes, for diagnosing and monitoring of electrical/cardiac activity and represents a substantial improvement regarding to the state of art.

Based on the above referred features, this multi-functional equipment was developed

for diagnosing and monitoring of electrical/cardiac activity, which will be described in details, related to the attached drawings.

Figure 1 is a general view of a blocked diagram of the equipment of the invention, showing its main components;

Figure 2 is a status diagram which shows the ECG mode, wherein the straight lines mean "Status transition", the dotted lines mean "Data transmission by transtelephonic communication" and the hatched lines mean "Data transmission by infrared communication";

Figure 3 is a status diagram, which shows the SAECG mode, wherein the straight line means "Status transition" and the hatched line means "Data transmission by infrared communication";

Figure 4 is a status diagram, which shows the event recorder mode, wherein the straight line means "Status transition", the dotted line means "Data transmission by transtelephonic communication"

and the hatched line means "Data transmission by infrared communication";

Figure 5 is a status diagram, which shows the Holter mode, wherein the straight line means "Status transiton", the dotted line means "Data transmission by transtelephonic communication" and the hatched line means "Data transmission by infrared communication".

In accordance with what was illustrated in the above figures, the equipment of this invention enables that those data to be worked can be stored in Compact Flash/PCMCIA type cards, which make easier the information carrying and the data reading by a PC type computer.

Therefore, the present equipment is more pratical because of its smaller size, which can be classified as totally portable.

The communication types with PC are the following:

1.Data storage cards/PCMCIA - disconnected from the patient;

2.Infrared Rays - connected to the patient; and

3.Transtelephonic - connected to or disconnected from the patient,

and all the equipment operation is carried out by using the button 3.

Figure 1 shows a view of a general blocked diagram of the equipment, wherein can be observed a microcontroller 1, connected to a volatile memory as SRAM 2, which is activated by a button or switch 3.

Such a microcontroller 1 also provides an activity display 4 and it is connected to Amp blocks 5, each of them connected to electronic keys 6, the latter attached to the representative block of the inlets 7 (in number of 12).

On the other hand, the microcontroller 1 can operate with a Compact Flash type card 8 and includes the use of infrared communication, as that indicated in the block 8, as well as the transtelephonic communication through the loudspeaker 10.

The central component of the equipment is the microcontroller 1. This component comprises three A/D converters, one E/S serial port and two pulse width modulators, PWM, besides the support components to the CPU (RAM, ROM, temporizers and others).

The ECG signal is read from three inlets simultaneously of a total of twelve, already mentioned, i.e, there are four groups of three inlets. This gathering is made through the electronic

keys 6. The signals of the three inlets are amplified and injected into the three A/D converter inlets.

The microcontroller 1 controls the information flow, depending on the chosen operation mode, monitoring the effected events by using the button 3.

During the initializing, the uC records operation mode information in a specific area of the card for storing data 8, which justifies the necessity of being the mentioned card previously initialized in a PC computer.

The microcontroller 1 reads the ECG information through its A/D converters and transfers them to the volatile memory 2 till a data block is filled in an appropriate size. Only after this, the information is transferred to the card for the data storage 8.

Simultaneously, the information can be sent through the serial outlet to the infrared transmitter/receiver 9.

The other possibility is to send data through a pulse modulator to a loudspeaker 10.

The activity display shown in the diagram of the figure 1 is connected to another uC pulse modulator and blinks whenever all the time the equipament is in use.

All this circuit is fed by

two batteries (not shown), which adjust the voltage to operation values through a keyed source.

Concerning the operation modes, the four worldwide standards, related to the present equipment, are synthetized as follows:

ECG - this operation mode has the purpose of obtaining twelve ECG derivations, divided into four groups of three. Each derivation group is read during three seconds and then a new group is activated and read. This process is repeated for each one of the four groups and, at the end, one of the groups will be recorded during the pre-scheduled time defined by the physician.

SAECG - this operation mode aims at obtaining the electrocardiografic record of three derivations, with a sampling rate and a higher digital resolution, enabling the physician to observe features which are not shown in others operation modes. This mode is also known as "High resolution ECG".

EVENTS RECORDER - In this mode, the apparatus records, in a current manner, in volatile memory, by pre-established term 1, 2 or 3 , derivations from ECG. When the patient has a symptom, he activates the apparatus button. In this case, the equipment of the invention will record, to have the data stored in a card, a previous term and a farther term, which are programmed by the doctor. The purpose is to make easier na analysis of the relation symptom and ECG.

HOLTER - In this mode the apparatus records 2 or 3 ECG derivations of the patient during a 24 hour period. The data are analyzed in an automatized manner by a PC by means of a special software.

In order to activate the operation mode, it is necessary to insert the card, for data storage, into a PC PCMCIA compartment and prepare it for the desired mode, using a command of a specific software. In this process, all the prior data registered on the card will be deleted and the instructions concerning the operation mode, for example sampling frequency and A/D converter resolution, recorded thereof.

After the preparation phase, the card will be inserted in the equipment of the invention, which could be used in the patient when desired.

Each one of the operation modes will be described in details.

ECG Mode

Characteristics:

Analogical/digital convertion: from 200 to 1000 samples/second and 8 bit resolution.

Number of derivations: 12

Description:

The apparatus begins to operate when the button 3 is pushed.

During a second the

infrared communication will be automatically tried. If no reply is obtained from the infrared communication, it stops during this process.

The following derivations are read, in set of three, with three second cycles, up to complete the four groups in the following way: (D1, D2, D3), (Avr, AV1, Avf), (V1, V2, V3), (V4, V5, V6). At the end, the data from one of those four groups can be read during a pre-scheduled gap.

To stop a recording at any moment, the user should press the button 3 again.

To transmit the recorded data through the loudspeaker, it is necessary to push the button 3 during five seconds with the apparatus in the stand-by position, when no recording is made.

The figure 2 shows a blocked status diagram of the ECG mode, wherein the block A represents the equipment stand-by mode status. The circuit activity is minimum, which reduces the consumption to small values. At this stage, the following actions can be done:

- to begin the operation with PC, then the D status or the C status will be activated;
- to go to the B status by pushing the button until three bips will be issued from the loud-speaker (near five seconds).

The block B of figure 2 represents the status in which the apparatus transfers

all data recorded in the card, for data storage, to the loud-speaker and, through the telephone, to a receiver unit coupled to a PC.

The only action which could be done is to end this status and to stop the communication, returning to the status A by pushing the button again.

The block C of figure 2 represents the status in which the apparatus records the patient's electrocardiographic signals in the card, for data storage, and the only action that can be done is to end this status and to stop the recording, returning to the status A, by pushing again the button or when the recording time reached the pre-scheduled limit.

The block D of figure 2 represents the status in which the apparatus records the patient's electrocardiographic signals in the card, for data storage, and transfer them, simultaneously, to the PC through infrared communication and the only action that can be done is to stop the recording/communication, returning to the status A, by pushing again the button or when the recording time reached the pre-scheduled limit.

Figure 3 shows a SAECG mode blocked diagram, which will be set forth below:

SAECG mode

Characteristics:

Analogical/digital convertion: 1000 samples/second and 10 bit resolution.

Number of derivations: 3

Description:

The apparatus begins to operate when the button 3 is pushed.

The main derivation (x,y,z) is recorded until the button will be pushed again. The infrared communication is activated at any moment during the recording and it is controlled by a specific communication protocol, wherein the PC will only monitor the signals registered during the recording.

The block A of figure 3 represents the stand-by equipment status. The circuit activity is minimum, which reduce the consumption to really small values.

The only action to be done is to begin the operation, going to status B when the button 3 is pushed.

The block B of figure 3 represents the status in which the equipment records the electrocardiographic signal in the card, for data storage. The following actions can be done simultaneously with the recording:

- to transfer the ECG directly to the computer, in the event of beginning a infrared communication from PC. Said transmission will be stopped immediately if more activity is developed from PC.

- to end this status and to return to the A status, by pushing again the button 3 or if the recording time exceeds the pre-scheduled period.

Moreover, the figure 4 shows a blocked diagram of the event recorder mode, which will be further described.

EVENTS RECORDER mode

Characteristics:

Analogical/digital convertion: 100 or 200 samples/second and 8 bit resolution.

Number of derivations: 1, 2 or 3, which can be scheduled by an operator

Description:

The apparatus reads the derivation data and records in SRAM volatile memory, by using a "circular line" maintaining the electrocardiographic record of the last gap. This gap has a pre-scheduled term in the project (typically from 30 to 120 seconds).

If the button 3 is pushed for more than five seconds and the apparatus is not recording data on the card for storage 8, all the data already recorded on the card 8 will be transferred, by the loudspeaker, through transtelephonic communication, to a remote receiver connected to a PC.

If the button 3 is pushed for more than 3 seconds, the electrocardiographic signals will be transferred from the patient to the

loudspeaker and, through transtelephonic communication, to a remote receiver connected to a PC.

If the patient has a symptom, he will push button 3 and the event recording will begin as per the next description.

- The "circular line" data are transferred to the card.
- The patient's electrocardiographic signals are recorded directly on the card, for data storage 8, during a pre-scheduled gap by the physician or until the user pushes again the button 3.
- If the user pushes the button for more than 3 seconds, the data transferring, through the loud-speaker, simultanesouly to ECG recording on the card 8, will be carried out. In this case, if the button 3 is pushed again,the transtelephonic transmission will be stopped.
- At any moment a PC could require an infrared transmission. In this case, the equipment of the invention sends an ECG signal, simultaneously, through infrared way.

The blocked diagram of figure 4 shows the Event Recorder mode according to the invention. It will be set forth below.

The block A of mentioned figure 4 represents the mode, in which the equipment records cyclically the electrocardiographic signal in a volatile memory, keeping, therefore, a record of the last seconds of the cardiac activity. The following

actions are possible:

- to go to the status B, by quickly pushing the button 3; in this case the information of the volatile memory is recorded immediately on the card, for data storage 8.
- to transfer the ECG to the computer, in the event of PC will begin a communication.
- to transfer the ECG to the loudspeaker and through the telephone net to a receiver unit, by pushing the button 3 until one bip sound is heard (after 2 seconds).
- to go to status C by pushing the button 3 until three bip sounds are heard (near five seconds).

The block B of figure 4 represents the mode, in which the apparatus records the electrocardiographic signal on the card, for data storage 8. The following actions can be done simultaneously to the recording:

- to transfer the ECG to the loudspeaker by pushing the button 3 until one bip sound is heard (near 2 seconds).
- to end this status and to return to the A status, by pushing again the button 3 or when the recording time overcome the pre-scheduled term.

The block C of figure 4 represents the status in which the equipment of the invention transfers all data already recorded on the card, for data storage 8, to the loudspeaker and,

through telephone net, to a receiver unit coupled to a PC. In this case, only an action can be done, i.e, to return to A status by pushing the button or when all card data for data storage 8 were already transferred.

Figure 5 shows a status blocked diagram of the Holter mode, which will be now described.

HOLTER mode

Characteristics:

Analogical/digital convertion: from 200 to 1000 samples/second and 8 bit resolution.

Number of derivations: 2 or 3 to be scheduled by the operator

Description:

The apparatus begins its operation when the button is pushed.

The ECG data are recorded continuously on the card, for data storage 8, and stops only when no more space is available on the card when the batteries, which feed this equipment, are removed.

During recording, if the button is quickly pushed, a marking will be recorded. This marking enables the physician to find the pulsation period for a more in-depth analysis.

If the button is pushed for more than 3 seconds, it will begin the simultaneous ECG transmission, through the loud-speaker, to be transtelephonic transmitted to a remote receiver

connected to a PC. Said transmission would be stopped, by pushing the button 3 again.

At any moment, a PC may require an infrared transmission. In this case, the equipment sends the ECG signal simultaneously through infrared way.

Regarding the blocked diagram of figure 5, the block A represents the stand-by mode of the equipment. The circuit activity is minimum, which reduces the consumption to really small values and the only action to be done is to begin the operation going to the B status when the button is pushed.

The block B represents the equipment status, in which it records the electrocardiographic signal on the card, for the data storage 8. The following actions could be done simultaneously to the recording:

- to transfer the ECG directly to the computer, in the event of PC begins an infrared communication. This transmission is stopped immediately if there is no more PC activity;
- to transfer the ECG to the loud-speaker, by pushing the button 3 until one bip sound is heard (after 3 seconds);
- to record an event marking on the card, for data storage 8, in the case of the button is pushed quickly;

- to end this status and return to A status, by pushing again the button 3 or if the recording time exceeds the pre-scheduled period.

This equipment is the only one that joins the four electrocardiographic diagnosis methods in a sole system.

The proposed equipment, according to its features, besides providing an appropriated datamidia storage, it enables a continuous monitoring through two different communication modes.

Another feature of the equipment is its flexibility, since it is the only one known that enables communication with the four computer classic models, i.e, Desktop, Laptop, Notebook and Palmtop, in order to visualize, store and process data.

Coupled to any cellular telephone, it enables an on-line transmission of the continuous electrocardiographic monitoring to a central receiver unit from virtually any fixed or mobile point, e.g., ambulances, airplanes etc.

The modular structure is also another aspect of the present invention, so that, from a basic embodiment, the functionality and the system resources can be expanded, including new methods of diagnosing through analysis and data processing softwares and specific firmwares, without structural changes in the equipment, when a necessity or a new diagnosis prodecure developments comes on.

The equipment of the invention shows to be different from the state of art, since it is the only one ECG recorder with the following all together features:

- totally portable (pocket);
- data storage in Compact Flash/PCMCIA;
- allows a infrared transmission; and
- allows a telephonic transmission.

It is also the only one event recorder embodying the below mentioned characteristics:

- storage capacity up to 3 electrocardiogrphic derivations/until 1440 minutes. The present systems in use enable a storage only until 90 minutes of one derivation or 45 minutes of two derivations;
- allows a infrared transmission.

Moreover, in the specific Holter mode, this equipment embodies still other novelties:

- the possibility of transtelephonic monitoring
- the possibility of infrared monitoring.

In synthesis, it is a multicardiograph, which is the only system enabling four different electrocardiographic recording shapes, to be processed by a software, according to the four classic electrocardiographic diagnosis methods: conventional electrocardiogram, high resolution electrocardiography, Holter e symptomatical events

electrocardiography.

CLAIMS

1. Multi-functional equipment for diagnosing and monitoring of electrical/cardiac activity, which can operate in ECG, SAECG, Event Recorder and Holter modes and it consists of a microcontroller (1) connected to a SRAM (2) type volatile memory, being said microcontroller (1) activated by a button or switch (3); the microcontroller (1) also comprises an activity display (4) and it is connected to amplification blocks (5), each one connected to electronic keys (5), the latter connected to the inlets (7), which are twelve.

2. Multi-functional equipment for diagnosing and monitoring of electrical/cardiac activity, according to claim 1, wherein the microcontroller (1) can operate with a card for data storage (8), and it comprises the use of infrared communication (9), as well as the transtelephonic communication, through loudspeaker (10).

3. Multi-functional equipment for diagnosing and monitoring of electrical/cardiac activity, according to claim 1, wherein the microcontroller (1) comprises three A/D converters, one E/S serial port and two type PWM pulse width modulators, as well as the support components to the CPU, as per RAM, ROM, temporizer and others.

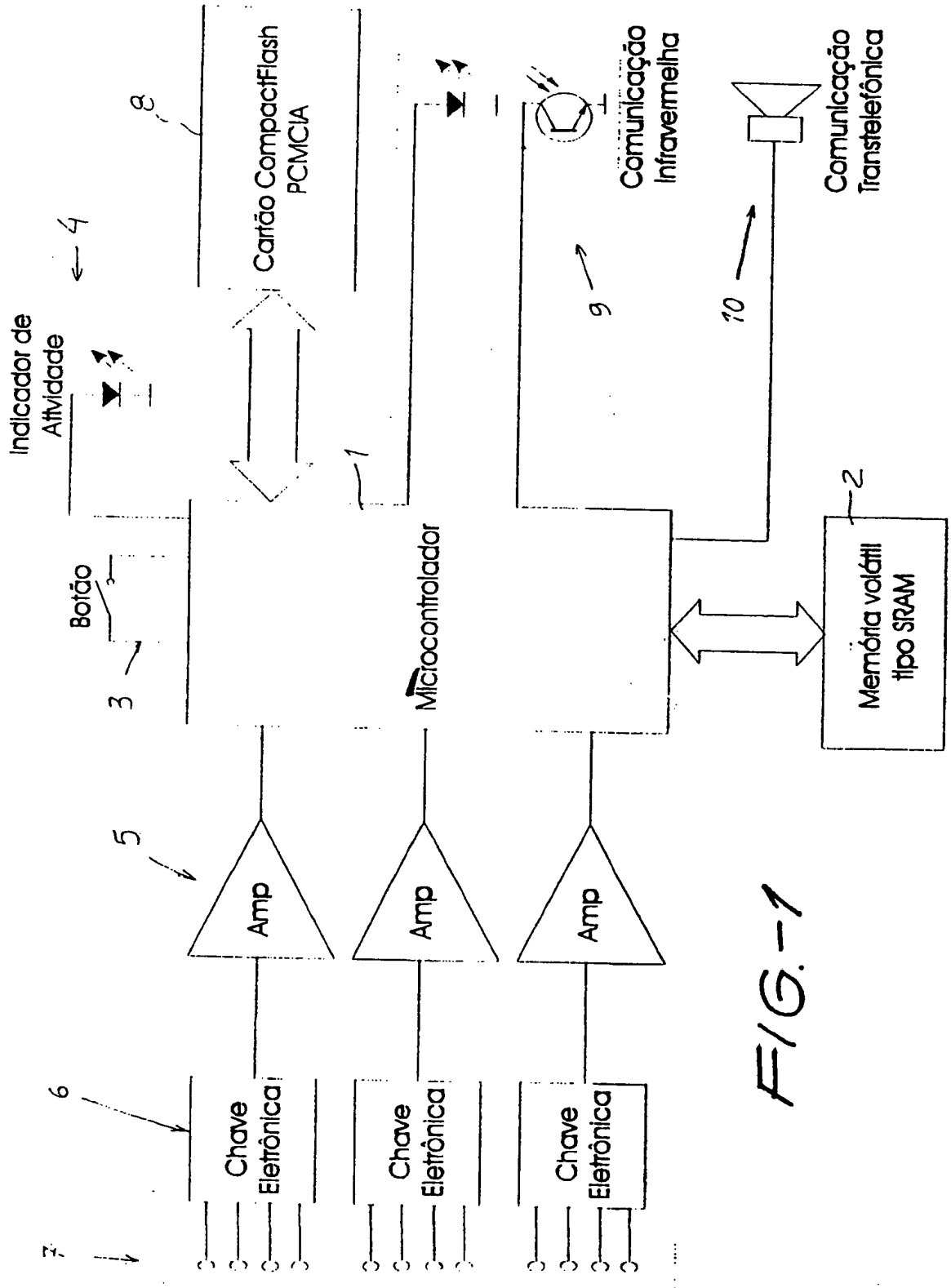
Indicador de Atividade
Botão
Cartão CompactFlash PCMCIA
Microcontrolador
Comunicação Infravermelha
Comunicação Transtelefônica
Memória volátil tipo SRAM
Amp
Amp
Amp
Chave Eletrônica
Chave Eletrônica
Chave Eletrônica
1
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FIG.-1

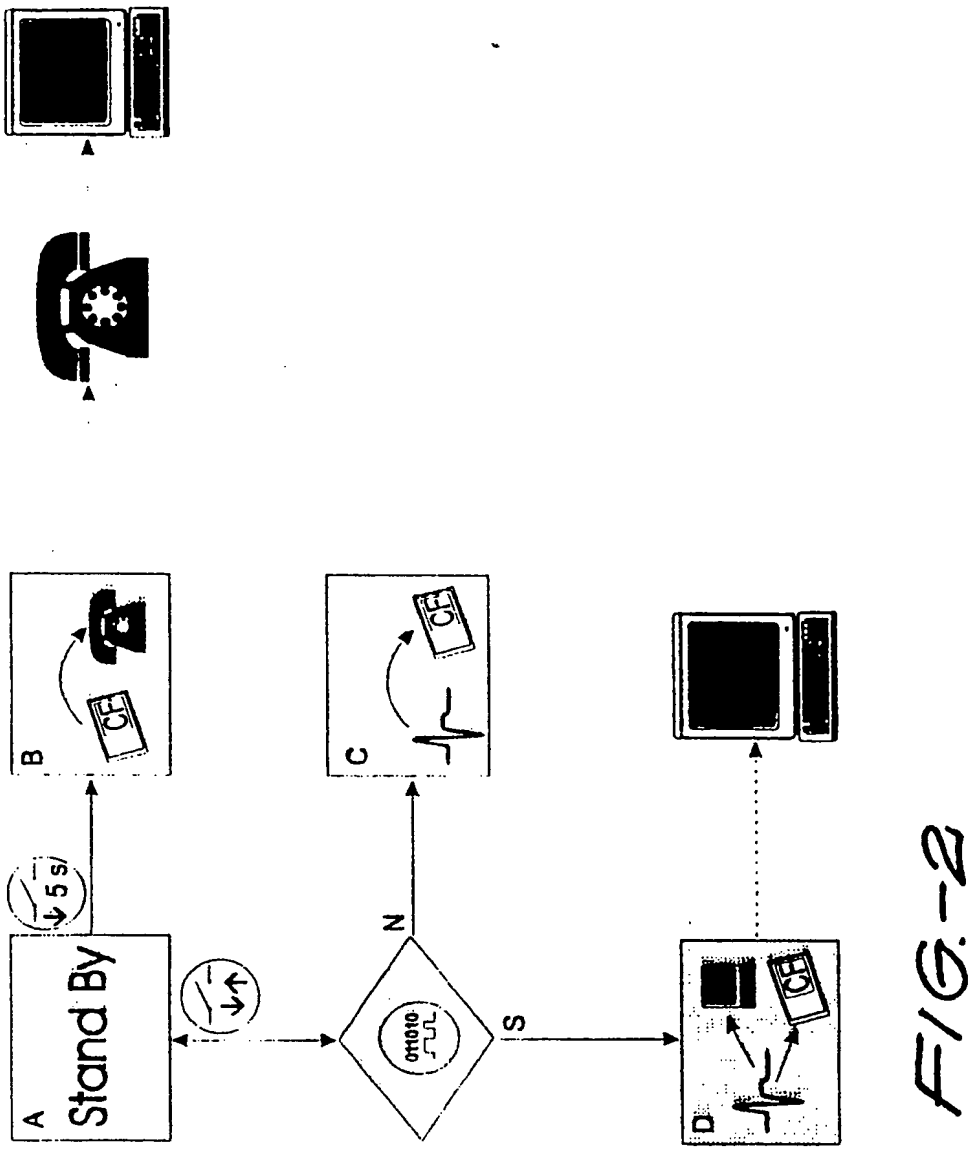

FIG-2

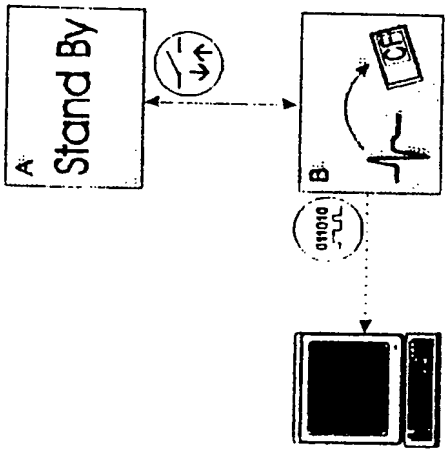

FIG-3

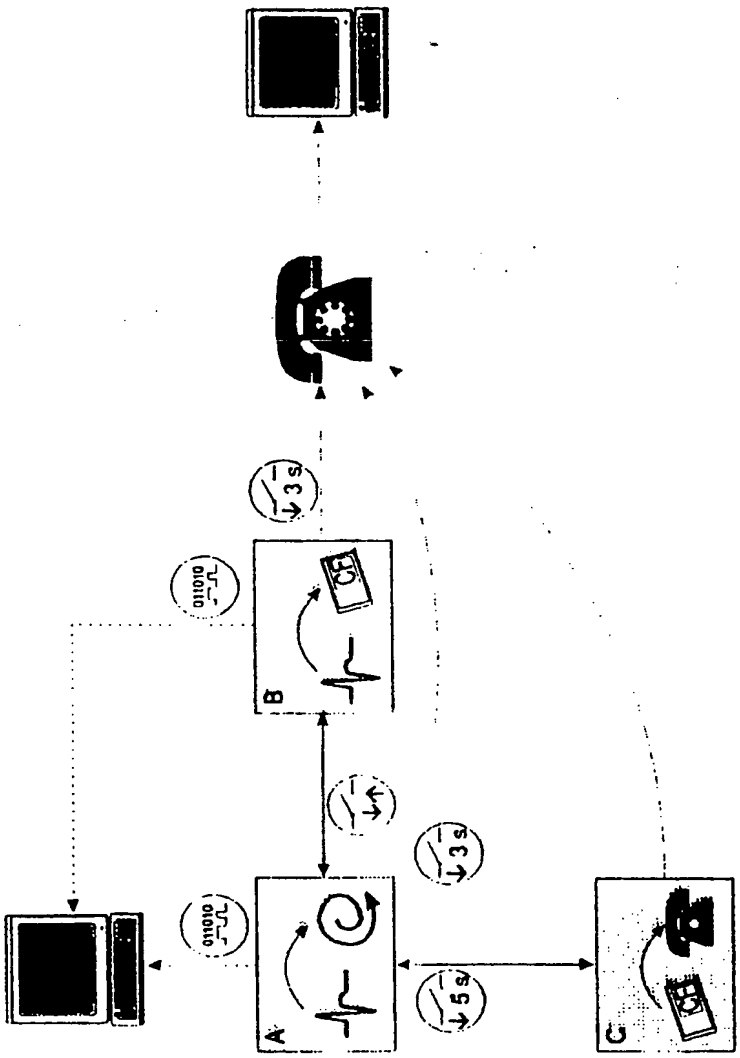

FIG. 4

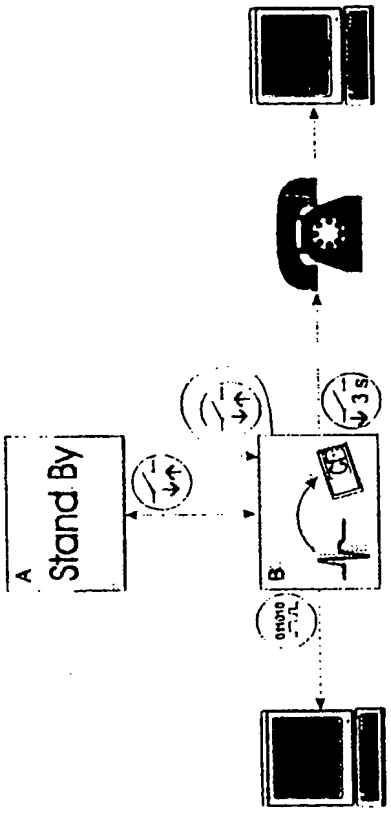

FIG-5

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/00098

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 5/04
US CL :600/509

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 600/509, 523

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,522,396 A (LANGER et al.) 04 June 1996, entire document.	1-3
Y	US 5,333,615 A (CRAELIUS et al.), 02 August 1994, entire document.	1-3
Y	US 4,624,263 A (SLAVIN) 25 November 1986, entire document.	1-3

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